

REMARKS

In response to the above Office Action and the noted objection to the sheet of photographs filed with the Reply of October 21, 2008, this is not a new drawing to be filed in this case, but rather is an attachment to the Declaration of Mr. Manabe filed with the Reply. Not only does the sheet of photographs not have the heading "New Sheet" as required by the Rules, but the Declaration specifically refers to it where it states:

The plastic ampoules produced in Experiments (sic Experiment) 1 and Comparative Experiment 1 were taken of a picture with the digital camera, respectively. Two pictures are shown in Fig. 1 and 2, respectively.

These two "pictures" are the "photographs" referred to by the Examiner in the Office Action. Withdrawal of the objection is therefore requested.

Applicants trust the Examiner considered these two photographs in Figs. 1 and 2 of the attachment to the Declaration when considering the Declaration because this is the best way to demonstrate the advantage of the external quality of the structure of Experiment 1 (structure of the invention) compared to the structure of Comparative Experiment 1 (a structure of the prior art). As noted in the Declaration:

The plastic ampoule shown in Fig. 1 has smooth surface and excellent external quality. On the other hand, the plastic ampoule shown in Fig. 2 has rough surface and inferior external quality in comparison to the one of Experiment 1.

If the Examiner did not consider these photographs when considering the Declaration, it is requested that he again consider it together with these two photographs.

In the Office Action the Examiner rejected claims 1, 3-7, 11 and 12 under 35 U.S.C. § 103(a) for being obvious over Meierhoefer in view of a newly cited

reference to Peiffer et al. (U.S. Patent No. 6,068,936), hereafter Peiffer. The withdrawal of the rejection of the claims over Meierhoefer in view of Takanashi and Itoh is appreciated. However, it is believed the claims as amended are not obvious over this newly cited combination of references for the following reasons.

Claim 1 has been amended to recite that "a thickness of the intermediate layer [of the three or more layers of the container body] is from 11.8 to 35.3% of a total thickness of the three or more layers." Support for this can be found in the Examples, and, in particular, in Examples 4 and 6 in Table 1 on page 41 of the specification.

In Example 4, the innermost layer has a thickness of 50 μm , the intermediate layer, which is a blend of a polyolefin and a polycycloolefin, has a thickness of 100 μm , and the outermost layer a thickness of 700 μm . Therefore, the thickness of the intermediate layer of Example 4 relative to the total thickness of the three or more layers is $100/850$ or 11.8%.

In Example 6, the innermost layer has a thickness of 50 μm , the intermediate layer a thickness of 300 μm (the sum of the inner, middle and outer layers), and the outermost layer a thickness of 500 μm . Therefore, the thickness of the intermediate layer of Example 6 relative to the total thickness of the three or more layers is $300/850$ or 35.3%.

As discussed in the previous Reply, Meierhoefer only describes a vial in which a container body has a single layer made of a plastic.

Peiffer relates essentially to a packaging material, twist-wrap film laminated film or a printed film made out of a polyolefin film. See claim 18 of Peiffer. The film contains at least one layer containing a polyolefin and a cycloolefin.

As an example of the polyolefin film, Peiffer discloses a transparent three-layer film having Outer layers B (the innermost layer and the outermost layer) consisting of a random ethylene-propylene copolymer and a Base layer A (the intermediate layer) consisting of a blend of isotactic polypropylene and norbornene homopolymer (See EXAMPLE 1 in column 11 of Peiffer). A total thickness of the transparent three-layer film is 20 μm and each thickness of the Outer layers B is 0.6 μm . Column 11, lines 22-26 of Peiffer. The thickness of Base layer A is 18.8 μm ($20\ \mu\text{m} - 0.6\ \mu\text{m} \times 2$). Consequently, the thickness of the intermediate layer is 94% of the total thickness of the film.

In contrast, the thickness of the intermediate layer of Claim 1 is from 11.8 to 35.3% of the total thickness (hereinafter "the total thickness") of the three or more layers.

According to Claim 1, an intermediate layer having a thickness of more than 35.3% of the total thickness is not included. Rather, in the structure of the claim 1, the inside and the outside layers are the main layers of the plastic ampoule and the intermediate layer is relatively-thin in comparison.

Therefore, not only can the plastic ampoule of the present invention prevent steam, gases other than steam, light rays or a drug from intruding into or leaking out of the ampoule, and also prevent a drug, a drug solution or a solvent contained in the ampoule from being absorbed in or adsorbed on an interior surface of the ampoule, but it can also retain good handleability and the strength required for holding a drug solution. Furthermore, the holder tab for wrenching off the fusion-bonded portion can be easily wrenched. As a result, the operability of the plastic ampoule is improved.

Neither Meierhoefer nor Peiffer teach any structure whether for a drug solution filling ampoule or not where the thickness of the intermediate layer is less than 35.3% of the total thickness of the three or more layers. This is because, unlike the present invention, the film of Peiffer is used as a packaging material such as a packaging film and is not used as a plastic ampoule for holding a drug solution. In other words, the use and the technical field of the present invention and that of Peiffer are entirely different.

Accordingly, even if Meierhoefer and Peiffer are combined as proposed by the Examiner, the combination does not teach Applicants' invention as now claimed. As required by M.P.E.P. § 2143.03, "all words in a claim must be considered in judging the patentability of that claim against the prior art" and it is apparent that none of the cited prior art shows the structure of the claimed intermediate layer. Also, as noted in M.P.E.P. § 2143.02, to support a conclusion that a claim would have been obvious, "all of the claimed elements" must have been known in the prior art.

Accordingly, it is submitted that neither claim 1 nor claims 3-7, 11 and 12 dependent therefrom are obvious over this combination of references. Its withdrawal as a ground of rejection of these claims is therefore requested.

Claims 13 and 15 were rejected under 35 U.S.C. § 103(a) for being obvious over Louviere in view of Peiffer. Claim 13 has been amended in a manner similar to claim 1.

The Examiner has acknowledged previously that Louviere lacks, inter alia, a disclosure of the claimed intermediate layer of a blend of a polyolefin and a polycycloolefin. While the Examiner believes this would be an obvious substitution in the disclosure of Louviere in view of Peiffer, Applicants have shown that Peiffer lacks the structure of the claimed intermediate layer and particularly the claimed limitation that

the thickness of the intermediate layer is from 11.8% to 35.3% of the total thickness of the three or more layers.

Accordingly, it is submitted that claim 13 and claim 15 dependent therefrom are also not obvious over this combination of references for the same reasons set forth above with respect to the product claims.

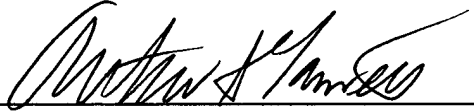
It is believed claims 1, 3-7, 11-13 and 15 are now in condition for allowance.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

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